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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/454,651      | 12/06/1999  | PETER S. LINSLEY     | 30436.30USD1        | 4031             |

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STEPHEN B. DAVIS  
BRISTOL-MYERS SQUIBB COMPANY  
PATENT DEPARTMENT  
P O BOX 4000  
PRINCETON, NJ 08543-4000

EXAMINER

GAMBEL, PHILLIP

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 06/24/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/454651

Applicant(s)

LINSLEY ET AL

Examiner

GANGEL

Art Unit

1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 3/27/01
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 38, 40, 43, 44 is/are pending in the application.
- 4a) Of the above claim(s) 38, 40, 43, 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 38, 40, 43, 44 is/are allowed.
- 6) ☒ Claim(s) 38, 40, 43, 44 is/are rejected.
- 7) ☐ Claim(s) 38, 40, 43, 44 is/are objected to.
- 8) ☐ Claim(s) 38, 40, 43, 44 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 3/27/01 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on 3/27/01 is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. 09/454651.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☒ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). 09/454651
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 09/454651 6) ☐ Other:

### DETAILED ACTION

1. Applicant's amendment and declaration, filed 3/27/02 (Paper Nos. 15 /1 6), have been entered.  
Claims 11-19, 39, 41 and 42 have been canceled.  
Claims 1-10 and 20-37 have been canceled previously.

Claims 38 and 40 have been amended.  
Claims 43-44 have been added.

Claims 38, 40 and 43-44 are pending and being acted upon.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.  
This Office Action will be in response to applicant's arguments, filed 3/27/02 (Paper No. 15).  
The rejections of record can be found in the previous Office Action (Paper No. 13).
3. Applicant's amendment and declaration, filed 3/27/02 (Paper Nos. 15 /1 6), have placed this application in compliance with the Sequence Rules.
4. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84.  
Please see the form PTO-948 previously sent in Paper No. 13.

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

#### B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

#### Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

11. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

5. The previous rejections under 35 U.S.C. 112, first and second paragraphs, enablement, written description and indefiniteness have been obviated by applicant's amended /canceled claims, filed 3/27/02 (Paper No. 15).

6. Claims 38, 40 and 43-44 are rejected under 35 U.S.C. § 102(e) as being anticipated by Linsley et al. (U.S. Patent No. 5,580,756) essentially for the reasons of record set forth in the previous Office Action (Paper No. 13).

Linsley et al. teach the use of B7 and B7 fusion proteins to inhibit neoplasia (see entire document, including Summary of the Invention, Detailed Description of the Invention such as columns 5-11 and Uses In Vitro and In Vivo, particularly columns 12-13).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced B7 molecules to regulate CD28 positive T cell responses and immune responses mediated by T cells.

It is noted that U.S. Patent No. 5,580,756 has priority back to US 07/498,949, filed March 26, 1990.

Applicant's arguments, filed 3/27/02 (Paper No. 15), have been fully considered but are not found convincing essentially for the reasons of record set forth in the previous Office Action (Paper No. 13).

Applicant argues that the invention is anticipated only if all elements of the claimed invention are present in a product or process discloses expressly or inherently in a single prior reference.

Applicant acknowledges that Linsley et al. teach using B7 to regulate CD28 positive T cell responses and immune responses mediated by T cells.

However, applicant argues that Linsley et al. does not describe or suggest that B7 is a ligand for CTLA4 receptor nor methods to regulate CTLA4 positive T cell responses.

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Therefore, methods comprising the administration of B7 in vivo to regulate CD28 positive T cell responses and immune responses mediated by T cells, as acknowledged by applicant, must have the inherent property of regulating CTLA4 positive T cell responses. T cell express both CD28 and CTLA4.

When a claim recites using an old composition or structure (e.g. B7) and the use is directed to a result or property of that composition or structure (regulating CD28 positive / CTLA4 positive T cell responses and immune responses mediated by T cells), then the claim is anticipated. See MPEP 2112.02.

The claim language of inhibiting CTLA4 positive T cell responses is only a statement of purpose and intended result. The expression of inhibiting CTLA4 positive T cell responses does not result in a manipulative difference in the steps of the claims, wherein B7 is administered in vivo to regulate T cell and/or immune responses.

Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); Bristol-Myers Squibb Co. v. Ben Venue Laboratories Inc. 58 USPQ2d 1508 (CAFC 2001).

See MPEP 2112-2112.02

Applicant's arguments are not found persuasive.

7. No claim allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

*Phillip Gambel*

Phillip Gambel, PhD.

Primary Examiner

Technology Center 1600

June 20, 2002